B. Support for Claims

Claims 109-143, added by present amendment, are dependent on claim 93, and are directed to different types of aprotic solvents that may be used in the methods to prepare the solvent vehicles (embodied by claims 109-115); different types of secondary solvents (embodied by claims 116-130); and different components that can comprise the solvent vehicles (embodied by claims 131-143). Claims 144-149, added by present amendment, are dependent on claim 98 and describe different embodiments of pharmaceutically acceptable solvents. These claims are adequately supported by the specification with particular support found page 5, lines 8-28; at page 10, lines 6-24, page 11, lines 1-6, at page 12, lines 21- page 13 lines 1-5, and lines 23-29, at page 16, Table 1.

Claims 109-115 describe embodiments of the aprotic solvent. Support for these claims can be found throughout the specification as filed, with particular support found at least at page 8, lines 21-22, at page 9, lines 12-15, at page 10, lines 19-21, at page 13, lines 2-5, at page 13, lines 25-27, page 15, lines 3-4 and Table 1.

Claim 116-130 describes embodiments of the secondary solvent. Support for these claims can be found throughout the specification as filed, with particular support found at least at page 13, lines 26-28, page 14, line, 26, at page 7, line 8, page 10, line 30, and at page 5, lines 19-21.

Claims 131-143 describes embodiments of solvent vehicle compositions. Support for these claims can be found throughout the specification as filed, with particular support found at least at page 15, lines 16-23, page 17, lines 25-28 and at page 20, Table 2.

Claims 144-149, depend on claim 98, and describe embodiments wherein the composition further comprises another pharmaceutically acceptable aqueous solvent. Support

for these claims can be found throughout the specification as filed, with particular support in original claim 98, and at page 5, lines 16-18.

No new matter is added by these amendments. Applicants request consideration of these claims.

II. RESPONSE TO RESTRICTION REQUIREMENT

In response to the Restriction Requirement imposed by the Examiner, Applicants elect, without traverse, to prosecute the Group IV claims, embodied by claims 93-99, and 106-149, which are directed to methods of preparing the solvent vehicles. Claims 109-149, added by the present amendment, are also directed to the Group IV invention and are specifically directed to different types of aprotic solvents that may be used in the methods (claims 109-115), different types of secondary solvents (claims, 116-130), different components of the solvent vehicles (claims 131-143) and different types of "pharmaceutically acceptable solvent" (claims 144-149). As set forth above these claims are adequately supported by the specification. Thus, Applicants request consideration of these claims.

III. RESPONSE TO SPECIES ELECTION REQUIREMENT

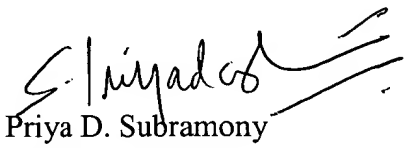
The Examiner has also entered a Species Election Requirement and required the election of a single species of secondary solvent from among: aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, lipid solution, parenteral or infusion fluid. Applicants traverse the species requirement. However, Applicants currently elect aqueous lipid emulsion as the species for initial examination. Current claims 93, 98, 99, 116, 117, 118, 119, 120, 121, 122, 133, 134, 135, 136, 137, 141, 142, 143, 144, 145, 146, 147, 148, and 149 encompass the elected species. If any generic claim, such as any of current claims 93-99, 106-

108, 116, or 131-143, is found allowable, Applicants reserve the right to reintroduce claims to the remaining species in the present case.

IV. CONCLUSION

Applicants respectfully request favorable consideration of this case in view of the above. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512)-536-3067.

Respectfully submitted,



Priya D. Subramony
Reg. No. 50,939
Agent for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
512-536-3067
Date: February 5, 2003

APPENDIX A

INDICIA OF CLAIM AMENDMENTS

109. (new) The method of claim 93, wherein said aprotic solvent comprises N,N-dimethylacetamide, castor oil, dimethylsulfoxide, 1,2,-propylene-diol, glycerol or polyethylene glycol-400.

110. (new) The method of claim 109, wherein said aprotic solvent comprises N,N-dimethylacetamide.

111. (new) The method of claim 109, wherein said aprotic solvent comprises castor oil.

112. (new) The method of claim 109, wherein said aprotic solvent comprises dimethylsulfoxide.

113. (new) The method of claim 109, wherein said aprotic solvent comprises 1,2,-propylene-diol.

114. (new) The method of claim 109, wherein said aprotic solvent comprises glycerol.

115. (new) The method of claim 109, wherein said aprotic solvent comprises polyethylene glycol-400.

116. (new) The method of claim 93, wherein said secondary solvent comprises aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, or lipid solution.

117. (new) The method of claim 116, wherein said secondary solvent comprises an aqueous lipid emulsion.

118. (new) The method of claim 117, wherein said aqueous lipid emulsion comprises emulsified fat particles of about 0.4 micron in diameter.

119. (new) The method of claim 117, wherein said aqueous lipid emulsion comprises an aqueous soy bean lipid emulsion.

120. (new) The method of claim 119, wherein said aqueous soy bean lipid emulsion comprises soy bean oil, lecithin, glycerin and water.

121. (new) The method of claim 117, wherein said aqueous lipid emulsion comprises a lipid component that includes at least one vegetable oil and at least one fatty acid.

122. (new) The method of claim 121, wherein said lipid component comprises at least about 5% by weight soybean oil and at least about 50% by weight fatty acids.

123. (new) The method of claim 116, wherein said secondary solvent comprises water.

124. (new) The method of claim 116, wherein said secondary solvent comprises saline solution.

125. (new) The method of claim 116, wherein said secondary solvent comprises dextrose solution.

126. (new) The method of claim 125, wherein said dextrose solution comprises 5% to 70% dextrose in water.

127. (new) The method of claim 126, wherein said dextrose solution comprises 5% or 10% dextrose solution.

128. (new) The method of claim 116, wherein said secondary solvent comprises glacial acetic acid.

129. (new) The method of claim 93, wherein said secondary solvent comprises a lipid solution.

130. (new) The method of claim 93, wherein said secondary solvent comprises a parenteral infusion fluid.

131. (new) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and polyethylene glycol-400.

132. (new) The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid and polyethylene glycol-400.

133. (new) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and aqueous lipid.

134. (new) The method of claim 133, wherein said aqueous lipid is an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

135. (new) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 1:10 volume ratio.

136. (new) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide diluted with 9 volumes 20% of an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

137. (new) The method of claim 134, wherein said solvent vehicle further comprises normal saline or 5% dextrose solution.

138. (new) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400 and 1,2-propylene diol.

139. (new) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide.

140. (new) The solvent vehicle of claim 139, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide in equal volume ratios.

141. (new) The method of claim 93, wherein said vehicle comprises glacial acetic acid, and wherein said vehicle further comprises anhydrous N,N,-dimethylacetamide, dimethylsulfoxide or an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

142. (new) The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

143. (new) The method of claim 142, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide, and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 2:6:3 volume ratio.

144. (new) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises water.

145. (new) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises saline solution.

146. (new) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises dextrose solution.

147. (new) The method of claim 146, wherein said dextrose solution comprises 5% to 70% dextrose in water.

148. (new) The method of claim 147, wherein said dextrose solution comprises 5% or 10% dextrose solution.

149. (new) The method of claim 98, wherein said secondary solvent comprises a parenteral infusion fluid.

APPENDIX B

LIST OF PENDING CLAIMS

93. A method for preparing a pharmaceutically acceptable solvent vehicle comprising:

a) obtaining a pharmaceutically acceptable dipolar aprotic solvent and/or acid;

b) mixing the dipolar aprotic solvent and/or acid in a pharmaceutically acceptable aqueous secondary solvent; and

c) removing the dipolar aprotic solvent and/or acid,

whereby the dipolar aprotic solvent and/or acid is eliminated or virtually eliminated from the solvent vehicle.

94. The method of claim 93, where the acid is acetic acid.

95. The method of claim 93, where the dipolar aprotic solvent and/or acid is virtually eliminated from the solvent vehicle.

96. The method of claim 93, where removing the dipolar aprotic solvent and/or acid is by lyophilization.

97. The method of claim 93, further comprising reconstituting the composition by the addition of a pharmaceutically acceptable aqueous solvent.

98. The method of claim 97, wherein said pharmaceutically acceptable aqueous solution comprises water, saline solution, dextrose solution, aqueous lipid emulsion, glacial acetic acid, or lipid solution.

99. The method of claim 93, further comprising the step of dissolving pimaricin in said dipolar aprotic solvent and/or acid prior to mixing in a pharmaceutically acceptable aqueous secondary solvent.

106. The method of claim 93, wherein the dipolar aprotic solvent or acid is eliminated.

107. The method of claim 93, wherein the removing dipolar aprotic solvent or acid removes 95% of the dipolar aprotic solvent or acid.

108. The method of claim 107, wherein the removing dipolar aprotic solvent or acid removes 99% of the dipolar aprotic solvent or acid.

109. The method of claim 93, wherein said aprotic solvent comprises N,N-dimethylacetamide, castor oil, dimethylsulfoxide, 1,2,-propylene-diol, glycerol or polyethylene glycol-400.

110. The method of claim 109, wherein said aprotic solvent comprises N,N-dimethylacetamide.

111. The method of claim 109, wherein said aprotic solvent comprises castor oil.

112. The method of claim 109, wherein said aprotic solvent comprises dimethylsulfoxide.

113. The method of claim 109, wherein said aprotic solvent comprises 1,2,-propylene-diol.

114. The method of claim 109, wherein said aprotic solvent comprises glycerol.

115. The method of claim 109, wherein said aprotic solvent comprises polyethylene glycol-400.

116. The method of claim 93, wherein said secondary solvent comprises aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, or lipid solution.

117. The method of claim 116, wherein said secondary solvent comprises an aqueous lipid emulsion.

118. The method of claim 117, wherein said aqueous lipid emulsion comprises emulsified fat particles of about 0.4 micron in diameter.

119. The method of claim 117, wherein said aqueous lipid emulsion comprises an aqueous soy bean lipid emulsion.

120. The method of claim 119, wherein said aqueous soy bean lipid emulsion comprises soy bean oil, lecithin, glycerin and water.

121. The method of claim 117, wherein said aqueous lipid emulsion comprises a lipid component that includes at least one vegetable oil and at least one fatty acid.

122. The method of claim 121, wherein said lipid component comprises at least about 5% by weight soybean oil and at least about 50% by weight fatty acids.

123. The method of claim 116, wherein said secondary solvent comprises water.

124. The method of claim 116, wherein said secondary solvent comprises saline solution.

125. The method of claim 116, wherein said secondary solvent comprises dextrose solution.

126. The method of claim 125, wherein said dextrose solution comprises 5% to 70% dextrose in water.

127. The method of claim 126, wherein said dextrose solution comprises 5% or 10% dextrose solution.

128. The method of claim 116, wherein said secondary solvent comprises glacial acetic acid.

129. The method of claim 93, wherein said secondary solvent comprises a lipid solution.

130. The method of claim 93, wherein said secondary solvent comprises a parenteral infusion fluid.

131. The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and polyethylene glycol-400.

132. The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid and polyethylene glycol-400.

133. The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and aqueous lipid.

134. The method of claim 133, wherein said aqueous lipid is an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

135. The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 1:10 volume ratio.

136. The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide diluted with 9 volumes 20% of an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

137. The method of claim 134, wherein said solvent vehicle further comprises normal saline or 5% dextrose solution.

138. The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400 and 1,2-propylene diol.

139. The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide.

140. The solvent vehicle of claim 139, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide in equal volume ratios.

141. The method of claim 93, wherein said vehicle comprises glacial acetic acid, and wherein said vehicle further comprises anhydrous N,N,-dimethylacetamide, dimethylsulfoxide or an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

142. The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.

143. The method of claim 142, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide, and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 2:6:3 volume ratio.

144. The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises water.

145. The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises saline solution.

146. The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises dextrose solution.

147. The method of claim 146, wherein said dextrose solution comprises 5% to 70% dextrose in water.

148. The method of claim 147, wherein said dextrose solution comprises 5% or 10% dextrose solution.

149. The method of claim 98, wherein said secondary solvent comprises a parenteral infusion fluid.